UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

AGA Medical Corp.,

Plaintiff,

v.

Civil No. 10-3734 (JNE/JSM)
ORDER

W. L. Gore & Associates, Inc.,

Defendant.

J. Derek Vandenburgh, Alan G. Carlson, R.J. Zayed, Tara C. Norgard, and Samuel T. Lockner, Carlson, Caspers, Vandenburgh, Lindquist & Schuman, P.A., appeared for Plaintiff AGA Medical Corp.

Matthew Blackburn, Zachary Silbersher, and Jennifer Kenedy, Locke Lord LLP, and James Poradek, Faegre Baker Daniels LLP, appeared for Defendant W. L. Gore & Associates, Inc.

AGA Medical Corp. brought this action against W. L. Gore & Associates, Inc., for patent infringement. W. L. Gore asserted counterclaims for declarations of noninfringement and invalidity. The patent-in-suit is U.S. Patent No. 5,944,738 (filed Feb. 6, 1998). The case is before the Court to construe disputed terms pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

I. BACKGROUND

A human heart has two sides separated by an inner wall, the septum. Each side has an upper chamber, an atrium, that collects blood as it flows into the heart and a lower chamber, a ventricle, that pumps blood from the heart to either the lungs or other parts of the body. The right side of the heart pumps oxygen-depleted blood to the lungs. The left side of the heart pumps oxygen-rich blood to other parts of the body.

A septal defect is a hole in the septum. Septal defects vary in size, shape, and location. A septal defect allows oxygen-rich blood to mix with oxygen-poor blood. For example, an atrial septal defect is a hole in the part of the septum that separates the atria. An atrial septal defect allows oxygen-rich blood to flow from the left atrium into the right atrium instead of the left ventricle. Consequently, oxygen-rich blood is pumped back to the lungs instead of other parts of the body. Another septal defect, known as a patent foramen ovale, is a flap or valve-like opening in the part of the septum that separates the atria. It allows blood to flow in either direction between the atria.

According to the '738 Patent's Background of the Invention, "the present invention relates to a low profile occlusion device for non-surgical treatment of a patient having a Patent Foramen Ovale . . . and resulting paradoxical cerebral emboli. The device made in accordance with the invention is capable of automatically adjusting to a septal defect having eccentric openings and is particularly well suited for delivery through a catheter or the like to a remote location in a patient's heart or in an analogous vessel or organ within a patient's body." '738 Patent, col.1, ll.8-17. The '738 Patent contains thirty claims. Three are independent: claims 1, 13, and 20. AGA Medical asserts that W. L. Gore infringed claims 20, 23, 25, 27, and 30. The asserted claims appear below. Disputed limitations are emphasized.

> **20.** A collapsible medical device, comprising two enlarged diameter portions and ***a flexible central portion interconnecting the two enlarged diameter portions*** wherein said flexible central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device having a proximal end and a distal end, wherein at least one of the proximal and distal end includes ***means for securing said device to a delivery system***, said device having a collapsed configuration for delivery through a channel in a patient's body.
>
> **23.** The device as recited in claim **20**, wherein said flexible central portion is shaped to form a ***resilient*** portion to thereby pull the two enlarged diameter portions toward the other.

25. The device as recited in claim **20**, wherein a ***separation distance between the two enlarged diameter portions*** is less than ***a thickness of a patient's atrial septum***.

27. The medical device as recited in claim **20**, wherein said means for securing includes ***means for attachment to a delivery device***.

30. The medical device as recited in claim **20**, wherein the flexible central portion is shaped to form a stretchable portion, wherein the flexible central portion stretches to adjust to ***a thickness of a patient's atrial septum*** while the two enlarged diameter portions remain in a preset configuration.

II. DISCUSSION

The construction of patent claims "is a matter of law exclusively for the court." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). "[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). Words of a claim are generally given their ordinary and customary meaning, which is the meaning that the term would have to a person of ordinary skill in the pertinent art at the time of the invention. *Id.* at 1312-13. "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, a court should look to the sources available to the public that show what a person of skill in the art would have understood the claim language to mean. *Id.* at 1314. "Those sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The claims provide substantial guidance as to the meaning of particular claim terms. *Id.* In some cases, the use of a term within the claim provides a firm basis for construing the term. *Id.* Other claims of the patent can be valuable sources of enlightenment as to the meaning of a claim term. *Id.* "Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* In addition, differences between claims can help determine the meaning of particular claim terms. *Id.* For example, a dependent claim that adds a particular limitation creates a presumption that the limitation is not present in the independent claim. *Id.* at 1314-15.

The claims do not stand alone, however, and "must be read in view of the specification, of which they are a part." *Id.* at 1315 (internal quotation marks omitted). The specification is "always highly relevant" to claim construction and usually is dispositive because it is "the single best guide to the meaning of a disputed term." *Id.* (internal quotation marks omitted).

In addition to the claims and specification, a court should consider the patent's prosecution history, if it is in evidence. *Id.* at 1317. The prosecution history can "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

Finally, a court may consider extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* (internal quotation marks omitted). Extrinsic evidence, however, is less significant than the intrinsic record in claim construction. *Id.* Dictionaries and treatises can be useful in claim construction. *Id.* at 1318. Dictionaries, particularly technical dictionaries, "endeavor to collect the accepted meanings of terms used in various fields of science and

technology." *Id.* Expert testimony may aid a court in a variety of ways: by providing background on the relevant technology; by explaining how an invention works; and by ensuring that a court's understanding of technical concepts and terms is consistent with that of a person of ordinary skill in the art. *Id.* Expert testimony that consists of conclusory, unsupported assertions as to the definition of a claim term is not useful, however, and "a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" *Id.* (quoting *Key Pharm. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998)).

A. A flexible central portion interconnecting the two enlarged diameter portions

Claim 20 recites "a flexible central portion interconnecting the two enlarged diameter portions." AGA asserted that "[n]o construction is necessary" and that "[t]his claim term does not require a metal fabric." W. L. Gore offered this construction: "[a] flexible metal fabric portion that is located between and links together the two enlarged diameter portions." According to the Joint Claim Construction Statement, "[t]he parties agree that the central portion does not include either enlarged diameter portion, which is intended only to ensure that neither party can claim the exact same section of the medical device as being part of both the central portion and the enlarged diameter portions."

Metal fabric

The language of the '738 Patent's claims does not support W. L. Gore's assertion that the flexible central portion should be limited to a metal fabric. Whereas other claims explicitly recite "metal fabric," claim 20 does not. For instance, claim 1 recites:

> A collapsible medical device, comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end, each end having means for securing the metal fabric attached thereto, thereby inhibiting

> unraveling of the metal fabric, said metal fabric having a relaxed configuration having two enlarged diameter portions and a central portion disposed between the two enlarged diameter portions wherein said central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device further having a collapsed configuration for delivery through a channel in a patient's body.

Claim 13 recites:

> A collapsible medical device, comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end, each end having means for securing the metal fabric attached thereto, thereby inhibiting unraveling of the metal fabric, said metal fabric having a relaxed configuration having two enlarged diameter portions and a resilient portion disposed between the two enlarged diameter portions wherein said resilient portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device further having a collapsed configuration for delivery through a channel in a patient's body.

Claim 21 states: "The device as recited in claim **20**, wherein said device is formed from a metal fabric consisting of a plurality of woven metal strands." Although claims 1, 13, and 21 are directed to devices formed from or comprising a metal fabric, nothing about the disputed limitation in claim 20 indicates that the flexible central portion should be limited to a metal fabric. Were claim 20 to require a metal fabric, claims 20 and 21 would be indistinguishable.[1] *Cf. InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, No. 2010-1093, 2012 WL 3104597, at *5 (Fed. Cir. Aug. 1, 2012) ("The doctrine of claim differentiation is at its strongest in this type of case, where the limitation that is sought to be read into an independent claim already appears in a dependent claim." (internal quotation marks omitted)); *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1275 (Fed. Cir. 2012) ("The doctrine of claim

[1] In its responsive memorandum, W. L. Gore asserted that "AGA's claim differentiation argument fails because claims 20 and 21 are different." W. L. Gore explained: "Claim 21 requires that the ***entire device*** is formed from metal fabric 'consisting of a plurality of woven metal strands,' but under Gore's proposed construction claim 20 would only require a metal fabric ***central portion***. This difference alone overcomes the doctrine of claim differentiation." At the claim construction hearing, W. L. Gore asserted that the entire device, except for clamps, has to be a metal fabric.

differentiation, while not a hard and fast rule of construction, creates a presumption that the independent method claims do not contain this limitation, for the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." (internal quotation marks omitted)).

W. L. Gore relied heavily on the specification and the prosecution history to support its argument that the flexible central portion requires a metal fabric.[2] The specification addresses at length formation of the devices from a metal fabric, but the Court does not discern in it an indication that the flexible central portion must be limited to a metal fabric. *See Phillips*, 415 F.3d at 1316. The same is true of the prosecution history. Initially, claims 1 and 13 recited "a tubular metal fabric," claim 20 did not mention a metal fabric, and claim 21 recited "a continuous tubular metal fabric." The examiner rejected all claims "under the judicially created doctrine of double patenting":

> The subject matter claimed in the instant application is fully disclosed in the patent [U.S. Patent No. 5,725,552] and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A collapsible medical device comprises a continuous tubular metal fabric having a plurality of woven metal strands and means for securing each end of the metal strands, wherein the metal fabric has a configuration which includes two enlarged diameter portions and a reduced central portion.

The examiner also rejected all claims as anticipated by U.S. Patent No. 5,733,294 (Forber):

> In figures 6-8 and column 5, lines 54-67, Forber . . . discloses a collapsible device having a tubular metal fabric which includes woven metal strands 122, wherein the metal fabric has ends with means 123 to secure thereof so as to prevent unraveling of the metal fabric, wherein the metal fabric has a relaxed configuration which possesses first and second enlarged diameter portions and an elastic central portion, as recited in claims 1, 8, 13, 20-21.

Thus, the examiner assumed that claim 20 required a tubular metal fabric.

---

[2] According to W. L. Gore, "if claim 20 does not require a metal fabric central portion, then it is invalid for lack of written description and enablement." The Court expresses no opinion on this assertion.

In response to the examiner's rejection, the applicant amended claims 1 and 13 by deleting "tubular" from the description of the metal fabric. The applicant also indicated that claim 1's central portion, as well as claim 13's resilient portion, allows lateral movement of each of the two enlarged diameter portions with respect to the other. In claim 20, the applicant added "flexible" to the description of the central portion and indicated that the flexible central portion allows lateral movement of each of the two enlarged diameter portions with respect to the other. The applicant deleted "continuous tubular" from the description of the metal fabric in claim 21. In remarks explaining how the claims as amended were distinguishable from Forber and the '552 Patent, the applicant essentially repeated claims 1, 13, and 20, as amended. Thus, the applicant noted that claim 1 was "directed to a collapsible medical device comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end," that claim 13 was "directed to a collapsible medical device comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end," and that claim 20 was "directed to a collapsible medical device comprising two enlarged diameter portions and a flexible central portion interconnecting the two enlarged diameter portions." The applicant continued:

> Neither the '294 patent nor the '552 patent show or describe a collapsible medical device having a central portion that allows lateral movement of each of the two enlarged diameter portions with respect to the other. At best, the "central portion" of the '294 patent and/or the '552 patent allow the "enlarged diameter portions" to rotate around the "central portion" and with respect to each other. There is no suggestion and it does not appear that the "central portion" of either the '552 patent or the '294 patent would or could allow lateral movement of the "enlarged diameter portions" with respect to each other.
>
> It appears that the office action has incorrectly assumed that the center portion of the '294 and '552 devices are flexible or resilient. The teaching of the '294 patent does not describe the central portion of the metal fabric as being flexible or resilient. Rather the "central portion" is described in the '294 patent [Forber] as a rigid or radiopaque center band assembly 25, 125 or 225 which is fixed to the metal fabric.

> Thus, the rejection of independent claims 1, 13 and 20 and their corresponding dependent claims is not proper and the claimed invention cannot be said to be anticipated by the teachings of the '294 patent or the '552 patent.

The examiner allowed the claims as amended.

Although the applicant did not expressly contradict the examiner's assumption that claim 20 required a tubular metal fabric, "an applicant's silence regarding statements made by the examiner during prosecution, without more, cannot amount to a 'clear and unmistakable disavowal' of claim scope." *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1345 (Fed. Cir. 2005). As noted above, the applicant responded to the examiner's rejections by amending claims 1, 13, 20, and 21. The applicant noted that claims 1 and 13 were directed to devices comprising a metal fabric, but the applicant did not describe claim 20 in the same manner. Claim 21, which depends from claim 20, was amended to require formation of the device from a metal fabric instead of a continuous tubular metal fabric.[3] The applicant highlighted the inability of the central portions of Forber and the '552 Patent to allow lateral movement of the enlarged diameter portions with respect to each other, and the applicant asserted that the examiner had incorrectly assumed that the central portions of Forber and the '552 Patent were flexible or resilient. On this record, the Court does not discern a basis in the prosecution history to limit claim 20's flexible central portion to a metal fabric.

---

[3] As amended, claims 20 and 21 are:

> **20.** A collapsible medical device, comprising two enlarged diameter portions and a flexible central portion interconnecting the two enlarged diameter portions wherein said flexible central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device having a proximal end and a distal end, wherein at least one of the proximal and distal end includes means for securing said device to a delivery system, said device having a collapsed configuration for delivery through a channel in a patient's body.
>
> **21.** The device as recited in claim **20**, wherein said device is formed from a metal fabric consisting of a plurality of woven metal strands.

In short, the Court does not construe claim 20's flexible central portion to require a metal fabric.

Between

AGA's primary objection to "between" is one of claim differentiation. "'When different words or phrases are used in separate claims, a difference in meaning is presumed.' 'However, simply noting the difference in the use of claim language does not end the matter. Different terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper.'" *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009) (quoting *Nystrom v. TREX Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005)).

As noted above, claims 1 and 13 recite a central or resilient portion "disposed between the two enlarged diameter portions wherein said [central or resilient] portion allows lateral movement of each of said two enlarged diameter portions with respect to the other." Claim 20 does not use "between": "a flexible central portion interconnecting the two enlarged diameter portions wherein said flexible central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other." Claims that depend from claim 20 add limitations to the flexible central portion. For instance, in claim 23, the "flexible central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other." In claim 26, "a length of the flexible central portion is dimensioned such that a perimeter edge of the first enlarged diameter portion overlaps a perimeter edge of a second enlarged diameter portion." In claim 30, "the flexible central portion is shaped to form a stretchable portion, wherein the flexible central portion stretches to adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in a preset configuration."

According to the Summary of the Invention, "[t]he device of the present invention . . . includes two opposing spaced apart 'discs', patches, or retention skirts interconnected by a flexible or resilient central member. The central member flexes both laterally and in the fore and aft directions while providing an inward tension against each of the discs." '738 Patent, col.3, ll.13-18. A principal object of the invention is "to provide a device suitable for occluding a septal defect that is capable of automatically adjusting to eccentric openings of the septal defect while providing an inward tension on the occluding portions of the device." '738 Patent, col.3, ll.61-65. Another object of the invention is "to provide an occluding device having outer occluding portions and a flexible resilient central portion that pulls the outer occluding portions together." '738 Patent, col.4, ll.5-8. Discussing the '738 Patent's figures, the Detailed Description of the Preferred Embodiment states:

> When the device **10** is in a relaxed state, the discs **12** and **14** tend to overlap and the central portion **16** extends into the recess formed by the inner surface of the discs **12** and **14**. In this manner, when the discs **12** and **14** are pulled apart (see FIG. **3**) the spring-like action of the central portion **16** will cause the perimeter edge **22** and **24** of the corresponding disc to fully engage the sidewall of the septum (see FIGS. **11** and **12**).

'738 Patent, col.10, ll.6-13. In addition, the length of the central portion may be varied:

> Those skilled in the art will appreciate that the device **10** is sized in proportion to the shunt to be occluded. The diameter of each disc **12** and **14** may be varied as desired for differently sized openings in the septal wall. Further, the length of the resilient central portion may be varied depending upon the thickness of the septal wall, and may range between 4 to 40 mm.

'738 Patent, col.10, ll.49-55.

The Joint Claim Construction Appendix contains definitions of "central" from several dictionaries. The term essentially means in, at, or near the center. The medical device of claim 20 comprises "two enlarged diameter portions and a flexible central portion interconnecting the two enlarged diameter portions." The intrinsic evidence reveals that the '738 Patent uses

"central" in a manner that it consistent with its ordinary meaning. The parties have not focused on what, if any, clarity is achieved by construing "interconnecting" as "links together." The Court concludes that no construction of "a flexible central portion interconnecting the two enlarged diameter portions" is necessary.

B. Resilient

"Resilient" appears in claim 23's description of the flexible central portion: "wherein said flexible central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other." AGA offered this construction of resilient: "tending to spring back to a preset relaxed state upon removal of force." Asserting that "[i]t is unclear . . . why the dispute between the parties necessitates a construction of 'resilient,'" W. L. Gore asserted that the term should be construed as "spring-like."

The term "resilient" appears in several claims of the '738 Patent. In claims 3 to 7, the central portion is shaped, helically shaped, coiled, bent, or shaped, respectively, "to form a resilient portion to thereby pull the two enlarged diameter portions toward the other." Claim 13 recites "a resilient portion disposed between the two enlarged diameter portions wherein said resilient portion allows lateral movement of each of said two enlarged diameter portions with respect to the other." In claims 15 to 18, the resilient portion of claim 13 is shaped, helically shaped, coiled, or bent, respectively, "to thereby pull the two enlarged diameter portions toward the other." In claim 19, "the resilient portion may be flexed such that a first central axis of the first enlarged diameter portion is offset from a second central axis of the second enlarged diameter portion." In claims 23 and 24, the "flexible central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other." In claim 29, "the resilient portion is shaped to form a stretchable portion," and "the resilient portion stretches to

adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in the relaxed configuration."

The term "resilient" appears throughout the '738 Patent. For instance, the Abstract states that "[t]he device is preferably made from a continuous tubular metal fabric and includes two outer occluding portions and a resilient central, spring-like interconnecting member." The Summary of the Invention indicates that "[t]he device of the present invention . . . includes two opposing spaced apart 'discs', patches, or retention skirts interconnected by a flexible or resilient central member" and that "[t]he central member flexes both laterally and in the fore and aft directions while providing an inward tension against each of the discs." '738 Patent, col.3, ll.12-18. It also describes fabric, wires, or strands that may be used to make the device:

> When forming these intravascular devices from a resilient metal fabric a plurality of resilient strands or wires are provided, with the metal fabric being formed by braiding the resilient strands to create a resilient material. This braided fabric is then deformed to generally conform to a molding surface of a molding element and the braided fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the braided fabric in its deformed state. After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in the deformed state. The braided fabric so treated defines a relaxed state of a medical device which can be stretched or expanded and deployed through a catheter into a channel in a patient's body.

'738 Patent, col.3, ll.19-34. An object of the invention "is to provide an occluding device having outer occluding portions and a flexible resilient central portion that pulls the outer occluding portions together." '738 Patent, col.4, ll.5-8. The term "resilient" appears throughout the Detailed Description of the Invention in descriptions of the device and the flexible central portion. For instance, the device tends to resiliently return to a preferred relaxed shape when it exits a catheter:

> When the device exits the catheter, it will tend to resiliently return to a preferred relaxed shape. When the device springs back into this shape, it may tend to act

> against the distal end of the catheter effectively urging itself forward beyond the end of the catheter. This spring action could conceivably result in improper positioning of the device if the location of the device within a channel is critical, such as where it is being positioned in a shunt between two vessels. Since the threaded clamp can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled by the operator to ensure proper positioning during deployment.

'738 Patent, col.9, ll.3-15. Describing embodiments shown in the figures of the '738 Patent, the Detailed Description of the Invention states that "the central portion is resilient and pulls the outer discs towards each other" and that "the spring-like action of the central portion . . . will cause the perimeter edge . . . of the corresponding disc to fully engage the sidewall of the septum." '738 Patent, col.9, l.60 to col.10, l.13.

The Joint Claim Construction Appendix contains definitions of "resilient" from several dictionaries. The definitions include "able to spring back to an original form or position after compression, stretching, etc."; "springing back; rebounding"; "returning to the original form or position after being bent, compressed, or stretched"; "[r]eturning to an original position; springing back, recoiling, etc."; "[e]lastic; resuming an original shape or position after compression, stretching, etc."; "[c]apable of returning to an original shape or position, as after having been compressed"; and "springing back into shape, etc." Claim 23 uses "resilient" in a manner that is consistent with the term's ordinary meaning. The Court concludes that construction of the term is not necessary.

C. Separation distance between the two enlarged diameter portions

"Separation distance between the two enlarged diameter portions" appears in claim 25. AGA asserted that no construction of the term is necessary. According to W. L. Gore, the term is indefinite. Noting the '738 Patent's failure to define the term or to explain how to measure the distance, W. L. Gore contended the patent's "failure to provide an objective standard for determining the 'separation distance' is fatal to claim 25."

The Federal Circuit recently summarized the law of indefiniteness:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." "The review of indefiniteness under 35 U.S.C. § 112, paragraph 2, proceeds as a question of law without deference." "The question of whether the claims meet the statutory requirements of § 112 ¶ 2 is a matter of construction of the claims, and receives plenary review on appeal . . . . The claims as granted are accompanied by a presumption of validity based on compliance with, *inter alia*, § 112 ¶ 2."
>
> Claims need not be plain on their face in order to avoid condemnation for indefiniteness; rather, claims must only be amenable to construction. "[B]ecause claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet 'an exacting standard.'" Thus, "[a]n accused infringer must . . . demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art." "By finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of patent validity . . . and we protect the inventive contribution of patentees, even when the drafting of their patents has been less than ideal."

Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1365-66 (Fed. Cir. 2011) (alterations in original) (citations omitted), *cert. denied*, 132 S. Ct. 1541 (2012). W. L. Gore's arguments to date have not established that "separation distance between the two enlarged diameter portions" is indefinite. Without precluding W. L. Gore from asserting the term's indefiniteness at an appropriate time, the Court declines to construe the term at this time.[4]

D. A thickness of a patient's atrial septum

"A thickness of a patient's atrial septum" appears in claims 25 and 30. AGA asserted that no construction of the term is necessary. In the alternative, AGA contended that the term should be construed as "a thickness of the septal wall near the defect." According to W. L. Gore, "[t]his limitation requires that the device be deployed within a particular patient." W. L. Gore

[4] In its responsive memorandum, W. L. Gore stated that it "is content to preserve the issue of indefiniteness for later resolution at summary judgment or trial."

also maintained that the limitation is indefinite: "It is unclear what is to be measured, how it is to be measured, and where it is to be measured to determine the thickness of the atrial septum within a particular patient. The thickness of the atrial septum varies within a particular patient."

The Court declines to adopt W. L. Gore's proposed construction. The language of the disputed limitation does not address the device's deployment. It is "a thickness of a patient's atrial septum."

The Background of the Invention's discussion of prior art acknowledged that "the thickness of the septal wall near the defect" must be determined "[p]rior to implantation of these devices" "in order that an appropriately sized device may be provided." '738 Patent, col.2, ll.18-21. The Detailed Description of the Invention noted that "the length of the resilient central portion may be varied depending upon the thickness of the septal wall, and may range between 4 to 40 mm." '738 Patent, col.10, ll.53-55. W. L. Gore's arguments to date have not established that "a thickness of a patient's atrial septum" is indefinite. Without precluding W. L. Gore from asserting the term's indefiniteness at an appropriate time, the Court declines to construe the term at this time.

E. Means for securing said device to a delivery system

Claim 20 recites "means for securing said device to a delivery system." It is undisputed that this phrase is a means-plus-function limitation. The parties disputed both the claimed function and the corresponding structure. AGA proposed the following construction: "This is a means plus function limitation under 35 U.S.C. § 112, ¶6. The function is to secure the device to a delivery system. The corresponding structure is a threaded bore (and all equivalents thereof)." W. L. Gore offered the following construction:

This is a means plus function limitation under 35 U.S.C. § 112, ¶6.

> The function is to maintain a hold on the device to control the manner in which the device is deployed and to allow the device to be retracted and redeployed.
>
> The corresponding structure is a clamp having a threaded bore.

"An element in a claim for a combination may be expressed as a means . . . for performing a specified function without the recital of structure . . . in support thereof, and such claim shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. § 112 ¶ 6. "Construction of a means-plus-function limitation includes two steps. 'First, the court must determine the claimed function. Second, the court must identify the corresponding structure in the written description of the patent that performs the function.'" *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012) (quoting *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1332 (Fed. Cir. 2006)). "The statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim. Nor does the statute permit incorporation of structure from the written description beyond that necessary to perform the claimed function." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999). "Ordinary principles of claim construction govern interpretation of the claim language used to describe the function." *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002). "Failure to disclose adequate structure corresponding to the recited function in accordance with 35 U.S.C. § 112, paragraph 1, results in the claim being of indefinite scope, and thus invalid, under 35 U.S.C. § 112, paragraph 2." *Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision of Westchester, Inc.*, 336 F.3d 1308, 1319 (Fed. Cir. 2003); *see Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1329 (Fed. Cir. 2012) ("The indicated structure must limit the claim so as not to allow pure functional claiming.").

"'The court must construe the function of a means-plus-function limitation to include the limitations in the claim language, and only those limitations.'" *In re Aoyama*, 656 F.3d 1293, 1296 (Fed. Cir. 2011) (quoting *Cardiac Pacemakers*, 296 F.3d at 1113); *see Generation II Orthotics Inc. v. Med. Tech. Inc.*, 263 F.3d 1356, 1364-65 (Fed. Cir. 2001) ("When construing the functional statement in a means-plus-function limitation, we must take great care not to impermissibly limit the function by adopting a function different from that explicitly recited in the claim."). Claim 20 recites "means for securing said device to a delivery system." The Court concludes that the claimed function is securing the device to a delivery system. The Court declines to import limitations from the specification to further construe "securing" in the manner articulated by W. L. Gore. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1255-56 (Fed. Cir. 2011).

Having identified the claimed function, the Court turns to the corresponding structure. The Federal Circuit recently summarized the governing law:

> Our case law is clear that a means-plus-function claim limitation is limited to the structures disclosed in the specification and equivalents. A court must look to the specification to determine the structures that correspond to the claimed function. "[S]tructure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." If a patentee chooses to disclose a single embodiment, then any means-plus-function claim limitation will be limited to the single disclosed structure and equivalents thereof.

Mettler-Toledo, Inc. v. B-Tek Scales, LLC, 671 F.3d 1291, 1296 (Fed. Cir. 2012) (alteration in original) (citations omitted). "Section 112 paragraph 6 does not 'permit incorporation of structure from the written description beyond that necessary to perform the claimed function.' Structural features that do not actually perform the recited function do not constitute corresponding structure and thus do not serve as claim limitations." *Asyst Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1369-70 (Fed. Cir. 2001) (citation omitted).

The ’738 Patent clearly links or associates a clamp having a threaded bore to the claimed function:

- “The device has a relaxed low-profile configuration and *includes clamps that allow attachment of the device to an end of a delivery device or guide wire . . . . The guide wire or delivery catheter is then released from the clamp and removed.*” ’738 Patent, col.3, ll.44-58 (emphasis added).

- “A clamp is attached to an outer end of each occluding member, *wherein the clamps are adapted for coupling to the end of a guidewire or catheter for delivery to a pre-selected site within the patient.*” ’738 Patent, col.4, l.66 to col.5, l.3 (emphasis added).

- “By keeping the medical device attached to the delivery means, the operator can retract the device for repositioning relative to the abnormal opening, if it is determined that the device is not properly positioned within the shunt. A threaded clamp attached to the medical device allows the operator to control the manner in which the medical device is deployed out the distal end of the catheter. . . . Since the threaded clamp can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled by the operator to ensure proper positioning during deployment.” ’738 Patent, col.8, l.64 to col.9, l.15.

- “The ends 26 and 28 of the tubular braided metal fabric device 10 are welded or clamped together with corresponding clamps 30 and 32 to avoid fraying. Of course the ends may alternately be held together by other means readily known to those skilled in the art. Further, it is to be understood that other suitable fastening means may be attached to the ends 26 and 28 in other ways, such as by welding, soldering, brazing, use of biocompatable cementious material or in any other suitable fashion. *The clamps 30 and 32 tying together the wire strands at corresponding ends 26 and 28 also serve to connect the device to a delivery system*. In the embodiment shown, *the clamps 30 and 32 are generally cylindrical in shape and have a threaded bore 34* (see FIG. 7) for receiving the ends 26 and 28 of the metal fabric to substantially prevent the wires from moving relative to one another. *The threaded bore 34 is adapted to receive and engage a threaded distal end of a delivery device*.” ’738 Patent, col.10, ll.21-38 (emphasis added).

- “When the PFO occluding device is properly placed, the physician rotates the guidewire, *unscrewing the threaded distal end of the guidewire from the clamp 30 or 32 of the occluding device 10. The threads on the clamp are such that the rotation of the guidewire unscrews the guidewire from the clamp of the occluding device 10*, rather than merely rotating the occluding device. As noted above, the threaded clamp can also enable the operator to maintain a hold on the device during deployment, or enables the operator to control the spring action during deployment of the device to ensure proper positioning.” ’738 Patent, col.11, l.62 to col.12, l. 5 (emphasis added).

The Court concludes that the corresponding structure is a clamp having a threaded bore.

F. Means for attachment to a delivery device

Claim 27 recites "means for attachment to a delivery device." The parties' arguments are similar to those made with respect to claim 20's "means for securing said device to a delivery system." The Court concludes that the claimed function is to attach the device to a delivery device and that the corresponding structure is a clamp having a threaded bore.

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT the disputed terms and phrases are construed as set forth in this Order.

Dated: September 28, 2012

s/Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge